Paper 91

Mail Stop Interference
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Filed September 30, 2009

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

THOMAS L. CANTOR
Junior Party
(U.S. Patent Application 10/641,780),

v.

RICHARD J. ZAHRADNIK AND JEFFREY R. LAVIGNE
Senior Party
(U.S. Patent 6,838,264).
Patent Interference No. 105,575 (MPT)
(Technology Center 1600)

MEMORANDUM OPINION and ORDER
Decision on Motions

Before: FRED E. McKELVEY, *Senior Administrative Patent Judge* and SALLY GARDNER LANE and MICHAEL P. TIERNEY, *Administrative Patent Judges*.

TIERNEY, *Administrative Patent Judge.*

This interference is before a motions panel for a decision on preliminary motions. An oral argument took place in this interference, a transcript of which appears in the record. (Paper 87). Representing Junior Party Cantor was Matthew Kreeger. Senior Party Zahradnik was represented by Leonard Svensson.

I. Introduction

Human parathyroid hormone (PTH) is a protein that plays an important role in regulating calcium metabolism, calcium having an indispensable role in formation of bones and teeth, blood coagulation, muscle contraction, etc. (ZX 1019, ¶ 3). PTH serves to maintain a steady concentration of calcium in cells and surrounding fluids. Generally, high levels of PTH causes the release of stored calcium and low levels of PTH retards the release of calcium. (*Id.* at ¶ 4; ZX 1005, 1:18-27).

PTH assays attempt to quantify the amount of biologically active PTH due to its clinical significance. Unfortunately, PTH exists at extremely low levels (10 pg/ml to 65 pg/ml) and, compounding the problem, is the existence of inactive PTH fragments that interfere with the ability to detect biologically intact PTH. (ZX 1005, 1:46-59).

Biologically intact PTH is an amino acid peptide comprising a linear chain of eighty-four amino acids that can vary from one species to another, e.g., human to rat. (*Id.* at Fig. 2). Peptides sequences begin at an N-terminal (amino end) and end at the C-terminal (carboxy end).[1] The loss of the first two PTH amino acids at the "N-terminal" renders PTH inactive. (Paper 30, 1:16-18).

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[1] A simplified explanation of the PTH peptide is that PTH can be viewed as

The interference relates to a method of producing a PTH antibody, which can be used in a PTH assay. Antibodies are Y-shaped proteins that are used by the immune system to identify and neutralize foreign objects (antigens). The huge diversity of antibodies allows the immune system to recognize a wide diversity of antigens. Generally, the Y-tips of the antibody have a binding site that allows an antibody to identify and bind to a particular antigen, e.g., PTH, amidst millions of different molecules.

Both parties seek to produce antibodies that are specific for detecting whole PTH peptides but avoid detecting an interfering PTH peptide fragment in a biological sample. (Paper 28, 1:19-24).[2] The parties produce the antibodies by methods that involve administering a first peptide to an animal to generate antibodies, and, after a couple of unremarkable steps, a second peptide to isolate antibodies that detect intact PTH but avoid detecting interfering PTH fragments.

II. Summary of the Substantive Motions Awaiting Decision

Zahradnik and Cantor each have four motions awaiting decision. Generally, Zahradnik has filed three motions for judgment on patentability as well as a motion for no interference-in-fact. Cantor has filed motions to be accorded benefit of earlier filed applications, change the count to include a Cantor claim, correct inventorship and a contingent responsive motion to add claims.

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a train having 84 cars where the first car is represented by the engine (N-terminal) and the last car is represented by the caboose (C-terminal).

[2] A peptide is a polymeric chain of amino acids.

The parties' motions touch upon a wide variety of issues. We exercise our discretion and first analyze Zahradnik Substantive Motion 3, which alleges that all but one of Cantor's involved claims lack sufficient written descriptive support. 37 C.F.R. § 41.125(a) (Board to take up motions for decision in any order). We exercise our discretion in this manner as Zahradnik's written description motion focuses on what is arguably the novel feature of the invention, the use of a peptide having a particular length to help isolate and select a PTH antibody useful in detecting whole PTH but avoiding the detection of PTH fragments.

Cantor's claims employ a "second" peptide to select an antibody from antiserum where the antibody specifically detects whole PTH but avoids detecting an interfering PTH fragment. Cantor's claims, except claim 59, allow the second peptide to range in size from eight amino acids up to 33 amino acids.

As explained in detail below, Zahradnik has demonstrated by a preponderance of the evidence that Cantor's '780 specification fails to reasonably convey possession of the claimed genus of second peptides. Accordingly, we grant Zahradnik Motion 3.

Cantor's remaining claim, claim 59, employs a second peptide having four to eight amino acids (rat or human PTH 1-8 or at least four amino acids in the common sequence). Zahradnik's claims employ a second peptide having twelve amino acids (human, canine, rat, or bovine PTH 1-12). Cantor is on record that its remaining claim, claim 59, should not be involved in this interference and Zahradnik has taken the position that none of Cantor's claims interfere with Zahradnik's. Based upon our review of the record we agree with the parties and hold that the parties' remaining claims do not interfere-in-fact. A judgment terminating the interference on the

basis of no interference-in-fact between the parties' remaining claims accompanies this decision.

III. General Findings of Fact

The following findings of fact are supported by a preponderance of the evidence.

A. The Real Parties in Interest

1. Junior Party Cantor

1) The real party in interest for Cantor, U.S. Patent Application No. 10/641,780 is Scantibodies Laboratory Inc. (Paper 5).

2. Senior Party Zahradnik

2) The real party in interest for Zahradnik, U.S. Patent 6,838,264, is Immutopics, Inc. (Paper 10).

B. Accorded Priority Benefit

1. Junior Party Cantor

3) Cantor is involved in this interference based upon U.S. Patent Application No. 10/641,780, filed August 15, 2003. (Notice Declaring Interference, Paper 1, 3).

2. Senior Party Zahradnik

4) Zahradnik is involved in this interference based upon U.S. Patent No. 6,838,264, issued on January 4, 2005, based upon U.S. Application 09/730,174, filed December 5, 2000. (*Id.*).

5) Neither party was accorded priority benefit of an earlier filed patent application.

C. Count and Claim Correspondence

6) Count 1 is the sole count in interference and reads as follows:

Claim 1 of [Zahradnik] U.S. Pat. 6,838,264.

(Paper 1, 4).

7) Zahradnik '264 claim 1 reads as follows:

> 1. A method for producing an antibody to the N-terminal portion of (1-84) PTH useful in the determination of intact PTH 1-84 levels in a biological sample, the method comprising the steps:
>
> a) administering a first peptide antigen alone or a first peptide antigen coupled to a carrier protein to a host animal to induce antibody production against said first peptide antigen in said host animal, said first peptide antigen being selected from the group consisting of SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, SEQ ID NO. 6, (1-34) PTH and (1-84) PTH;
>
> b) monitoring antibody titer produced by said administration of said peptide antigen to said host animal;
>
> c) extracting antisera produced in said host animal; and
>
> d) isolating and selecting at least one antibody from said antisera extracted in step c) by affinity chromatography utilizing a second peptide antigen selected from the group consisting of SEQ ID NO. 3, SEQ ID NO. 4, SEQ ID NO. 5, and SEQ ID NO. 6.

(Zahradnik Clean Copy of Claims, Paper 9).

8) The claims of the parties are:

Zahradnik, U.S. Pat. 6,838,264: 1-5

Cantor, U.S. App. 10/641,780: 47, 49-51, 53-54 and 59-68

(*Id.*).

9) All of the parties' claims are designated as corresponding to Count 1. (*Id.*).

D. Notable Litigation in the Field of PTH Assays

10) There are at least three (3) commercially available intact PTH assay kits known in the art. The kits are available from Nichols, Scantibodies (Cantor) and Immutopics (Zahradnik). (ZX 1031, 262-63, Table 1).

11) Cantor filed a whistleblower lawsuit against Nichols alleging that Nichols Advantage Intact PTH Assay, among other things, was materially inaccurate as it provided elevated results. As a result of the lawsuit, the United States commenced civil and criminal investigations. Nichols' parent Quest Diagnostic settled the matter by paying $302 million to resolve the allegations, with Cantor receiving approximately $45 million. http://www.usdoj.gov/opa/pr/2009/April/09-civ-350.html

12) Scantibodies (Cantor) filed a patent infringement suit against Immutopics (Zahradnik) in the Central District of California. (ZX 1043, p. 1). The suit alleges that two Immutopics' assays infringe Cantor's U.S. Patent 6,689,566. (*Id.*).

13) Cantor's '566 patent issued from Cantor's U.S. Application

09/231,422. (Cantor Mot. 1, Paper 36, fact ¶ 1).

14) Cantor's involved '780 application is said to be a continuation of U.S. Application 09/344,639, which itself is said to be a continuation-in-part of Cantor's '422 application, now '566 patent. (*Id.* at fact ¶¶ 2-3).

15) The district court held that Scantibodies (Cantor's) '566 claims required an antibody that was *specific for* an initial peptide sequence of whole PTH wherein the initial sequence consists of PTH 2-8. (ZX 1043, 6).

16) The district court found that Immutopics antibodies bound an epitope of PTH (2-10) and (2-11) with higher affinity than to the PTH (2-8) region and that there is no reasonable dispute that such an antibody fails to meet the "specific for" claim limitation of the '566 patent. (*Id.*).

17) The district court also found that Immutopics did not meet certain dependent claim limitations, for example, Immutopics antibodies detect interfering (inactive) PTH fragments, such as PTH (7-84). (*Id.* at 8-11).

18) The district court held on summary judgment that Immutopics (Zahradnik) had demonstrated that their accused products did not infringe Scantibodies (Cantor's) '566 patent. (*Id.* at 14-15).

E. One of Ordinary Skill in the Art

19) The art to which this interference pertains is immunoassays. A person of ordinary skill in the art in the field of immunoassays would have had at least a Bachelor of Science degree in biochemistry or related subject with at least two years experience in immunochemistry. (Declaration of Dr. Woodhead, CX 2011, ¶ 18).

20) A person of ordinary skill in the art would have been familiar with biochemistry techniques such as protein purification, protein synthesis, antibody production and immunoassay design. (*Id.*).

21) Dr. Hutchinson, an immunological art expert, testifies on behalf of Zahradnik. Dr. Hutchinson received a Ph.D. in Biochemistry from the University of California Riverside and has practiced in the field of Clinical Biochemistry for over 23 years. (Dr. Hutchinson Declaration, ZX 1023, ¶ 1).

22) Dr. Woodhead, an immunological art expert, testifies on behalf of Cantor. Dr. Woodhead received a Ph.D. in Biochemistry from the University of Manchester in 1968. Dr. Woodhead has held numerous positions in the biotechnology industry and has received awards for his work in the field of immunoassay. (Dr. Woodhead Declaration, CX 2011, ¶¶ 1-8).

23) Both Cantor's expert, Dr. Woodhead, and Zahradnik's expert, Dr. Hutchinson, are qualified to testify as to the level and knowledge of one of ordinary skill in the art at the time of the invention. (CX 2011, ¶ 1, ZX 1023, ¶ 1).

IV. Analysis

Prior art conventional PTH assays failed to accurately distinguish between active PTH (1-84) peptide and inactive fragments thereof. (Zahradnik '264, ZX 1005, 1:51-57). Cantor and Zahradnik's PTH assays are said to be an improvement over previous assays in that the parties' assays employ antibodies that have a greater binding recognition for active PTH (1-84) and minimal cross reactivity to interfering, inactive fragments thereof. (*Id.* at 2:48-61 and Cantor Clean Copy of Claims, Paper 6, Claim 47). The parties' claims are directed to methods of producing the desired antibodies via a method involving a "second peptide," where the second peptides are PTH fragments having a specific structure, e.g., human PTH (1-8). The importance of the second peptide is explained in detail later in this decision, but generally it is the second peptide that allows one of ordinary skill in the art to obtain antibodies that preferentially bind intact PTH as opposed to inactive PTH fragments.

The rules authorize the Board to take up motions for decision in any order. 37 C.F.R. § 41.125(a). We have reviewed all of the motions awaiting decision and exercise our discretion by first analyzing Zahradnik Substantive Motion 3, which alleges that all but one of Cantor's claims are unpatentable for lack of sufficient written description. We exercise our discretion in this manner as Zahradnik Substantive Motion 3 focuses on Cantor's description of the second peptide, the use of which is critical in both parties' production of the desired antibodies.

A. Zahradnik Substantive Motion 3, Written Description

Zahradnik Substantive Motion 3 alleges that all of Cantor's involved claims, with the exception of claim 59, are unpatentable for lack of written

description under 35 U.S.C. § 112, first paragraph. (Paper 30). Cantor opposes. (Cantor Opposition 3, Paper 55).

Before addressing the merits of Zahradnik's motion we note that Cantor objects to Zahradnik Motion 3 on a procedural ground. Specifically, the Board authorized Zahradnik to file a motion attacking all of Cantor's involved claims as unpatentable for lack of written description. (Paper 23, 4:1-29 and Paper 24, 4:9). Zahradnik's motion however, alleges that all but one of Cantor's claims is unpatentable. Cantor contends that the motion should be dismissed for failing to make out a *prima facie* case for the relief requested and authorized by the Board. (Paper 55, 3:14-20). Zahradnik opposes Cantor's request stating, among other things, that the decision to take up less than all of the claims is within the discretion of the Board. (Paper 67, 3:1-4).

Based on the facts presented, we exercise our discretion and review the merits of Zahradnik Motion 3. In particular, Cantor has failed to demonstrate that it is prejudiced by Zahradnik's failure to allege that Cantor claim 59 is unpatentable for lack of written description such that the motion should be denied on procedural grounds.

1. Cantor's Involved Claims

Cantor claim 47 is Cantor's sole independent claim involved in the interference, with claims 49-51, 53, 54 and 59-68 depending there from. Cantor claim 47 reads as follows:

A method for producing an antibody for specifically detecting whole PTH_{1-84} *while avoiding detecting an interfering non-(1-84) parathyroid hormone fragment* in a biological sample, which method comprises:

a) administering a first peptide or protein immunogen to a host animal to induce antibody production against said first peptide or protein

immunogen in said host animal, said first peptide or protein immunogen being human, rat, bovine, or porcine PTH_{1-84};

b) monitoring antibody titer produced by said administration of said first peptide or protein immunogen to said host animal;

c) extracting antiserum produced in said host animal by said administration of said first peptide or protein immunogen; and

d) purifying said antiserum and selecting at least one antibody from said antiserum extracted in step c) by affinity chromatography utilizing a *second peptide* or protein immunogen, which comprises a contiguous portion of human, rat, bovine, or porcine PTH_{1-84} and *has the following characteristics*:

> *i) the N-terminal amino acid residue of said second peptide or protein immunogen starts at position 1 of said* PTH_{1-84}*; and*
>
> *ii) the C-terminal amino acid residue of said second peptide or protein immunogen ends at any position spanning position 8 through position 33 of said* PTH_{1-84}.

(Paper 6, emphasis added).

Cantor claim 59, which is not in dispute for Zahradnik Motion 3, reads as follows:

> The method of claim 47, wherein in step d), the second peptide or protein immunogen is human PTH_{1-8}, rat PTH_{1-8}, or a peptide having at least four amino acids in the common sequence of human and rat PTH_{1-8}.

(*Id.*). As is readily apparent, claim 59 differs from claim 47 in that claim 59 requires the second peptide be a human or rat PTH (1-8) or at least four amino acids in common between the two named sequences, i.e., any four amino acids in the range of PTH (2-8) as the first amino acid for human is serine whereas rat is alanine.[3]

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[3] While not mentioned by the parties, Cantor claim 59 does not further limit claim 47. Specifically, Cantor claim 47 requires the second peptide that the PTH peptide start at position 1. Cantor claim 59 does not require the peptide begin at position 1 as claim 59 allows the second peptide to be at least four

2. The Science Behind Cantor's PTH Antibody and Initial Peptide Sequence

Cantor's claims are directed to the production of an antibody that detects intact PTH (1-84) but avoids detecting an interfering non-(1-84) PTH fragment in a biological sample. The antibody is used in an assay to quantify the amount of intact PTH contained in the sample.

In a preferred embodiment, Cantor's PTH antibody is used in a sandwich assay. ('780 Specification, ZX 1003, 9:14-15). Generally, a sandwich assay works by sandwiching the desired antigen, here intact PTH, between two antibodies. Specifically, Cantor places a first "capture" antibody on a solid support. The capture antibody is specific for the C-terminal end of the PTH peptide. A second "signal" antibody is used that is specific for the N-terminal end of the PTH peptide where the signal antibody has a detectable label. (*Id.* at 15-20). One can then test a biological sample and quantify the amount of intact PTH by detecting labeled bound antibodies on the solid support. Provided below is Cantor Figure 2, which depicts the use of a labeled antibody in a sandwich assay:

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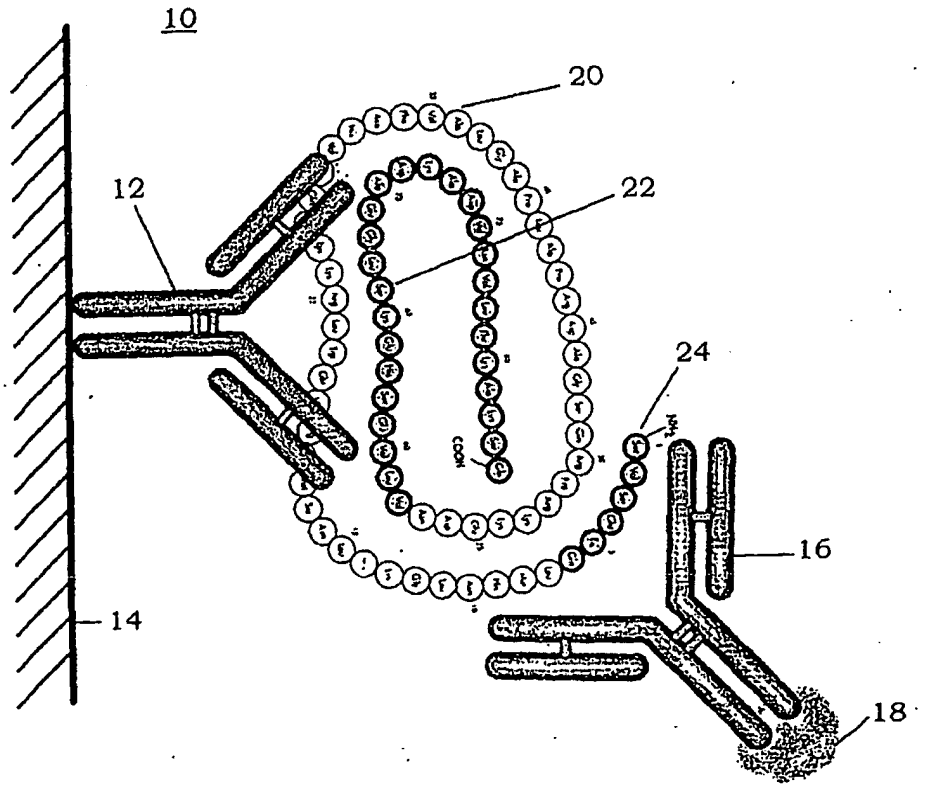
amino acids in the human/rat PTH(2-8) sequence. Furthermore, the smallest second peptide recited in independent claim 47 is eight (8) amino acids whereas claim 59 allows for the possibility of a second peptide having only four (4) amino acids.

CANTOR '780 FIGURE 2



Cantor Figure 2 depicts two antibodies, a capture antibody **12** and a signal antibody **16**. The capture antibody is bound to a solid support **14** and the signal antibody **16** contains a label **18**. A C-terminal PTH fragment is identified as **22** and the N-terminal adenylate cyclase activation region identified as **24**. (ZX 1003, 9:14-21).

The PTH protein (20, 22, 24) has 84 amino acids. PTH (1) is the first amino acid on the N-terminal side 24 and PTH (84) is the 84th amino acid on the C-terminal side 22.

PTH fragments can interfere with the detection of intact PTH. Interfering PTH fragments [e.g., PTH (3-84), . ., PTH (7-84), . . .,

PTH (34-84)] generally lack at least the first two amino acids, PTH (1-2). Cantor states that its antibody production method can obtain antibodies that detect the intact PTH (1-84) while avoiding the interfering PTH fragments. (See, e.g., Woodhead Dec., CX 2011, ¶ 22).

Cantor obtains its PTH antibody through what is essentially a two step process of generating antibodies and then isolating the desired antibodies. The step of generating antibodies generally involves injecting an animal, e.g., a goat, with PTH(1-84). (ZX 1003, 12:8-12). The animal produces antibodies in response to the peptide. The animal is then bled several months after the injection and an antiserum is derived by separating the red blood cells from the antiserum, which is rich in PTH antibodies. (*Id.* at 12:18-22).

To isolate PTH antibodies that favor the detection of intact PTH, as opposed to PTH fragments, a purification and isolation step is undertaken where the desired PTH antibodies are isolated from the antiserum by affinity purification. (*Id.* at 12:24 – 13:4). The affinity purification involves the use of the initial PTH sequence peptide ("second peptide" or "affinity purification peptide") where antibodies specific to the initial PTH sequence bind the initial sequence. The bound desired PTH antibodies are then removed from the antiserum. (*Id.*).[4]

Through the use of the initial peptide the claimed method is said to isolate the desired intact PTH while avoiding the detection of interfering non-(1-84) PTH fragments. Cantor's specification refers to the interfering fragments as "PIN" and defines the interfering fragments as including amino acid sequences ranging from PTH(3-84) to PTH(34-84). ('780 specification,

[4] A similar discussion regarding the teachings of Cantor's parent '566 patent is provided in ZX 1043 at 5:3 – 6:4.

ZX 1003, 5:11-14).

As acknowledged by Cantor's expert, the term "biological sample" as used in Cantor's application and claims means a sample from a patient to be tested to determine the level of intact PTH. One of ordinary skill in the art however, would not have known in advance the precise composition of interfering fragments were present in a particular biological sample to be tested. (Woodhead Dec., CX 2051, ¶¶ 14, 50).

Shorter initial peptides, e.g., PTH(1-8), are expected to be better at isolating antibodies that avoid detecting PTH fragments than larger initial peptides, e.g., PTH(1-33). (*Id.* at ¶¶ 29 and 33-34). Specifically, an PTH(1-8) affinity purification peptide is less likely to detect interfering fragments than PTH(1-9) which in turn is less likely to detect interfering fragments than PTH(1-10), etc. As explained below, the reason for this is that the larger the initial peptide the greater the chance that the antibody will bind to an interfering fragment.

Antibodies bind to what is referred to as an epitope. Proteins, such as the initial peptide, generally have epitopes containing about six (6) to eight (8) amino acids. (*Id.* at ¶ 20).[5] Thus, an antibody that binds to human PTH(1-8) could potentially bind to a human PTH(3-84) interfering fragment as PTH(1-8) and PTH(3-84) have a string of six amino acids in common. (*Id.* at ¶ 21). Conversely, fragments PTH(4-84) through PTH(8-84) would not be expected to bind to any significant extent to an antibody raised to PTH(1-8) as the fragments would not contain a complete six amino acid epitope in common with PTH(1-8) and by extension, fragments PTH(9-84)

[5] From this we infer that an antibody that binds to a PTH(1-8) initial peptide could bind to an amino acid region including 1-6, 2-7, 3-8, 1-7, 2-8 or 1-8. (*Cf.*, *Tizard, Immunology, An Introduction*, CX 2052).

through PTH(34-84) would also not be expected to bind. (*Id.* at 19-20).[6] An antibody that binds to PTH(1-33) however, will have a much greater chance of binding to fragments such as PTH(7-84), which is explicitly identified in Cantor '780 as a known fragment, as the fragment has more than enough amino acids to share a epitope in common with PTH(1-34). (Hutchinson Dec., ZX 1023, ¶ 6 and Woodhead Dec., ZX 2051, ¶¶ 10-11 and 20-21).

3. Legal Principles Relating to Zahradnik Motion 3

Generally, Zahradnik contends that Cantor's specification fails expressly, implicitly or inherently describe any initial peptide sequence ranging from PTH(1-9) through PTH(1-33) for antibody purification. (Paper 30). Cantor opposes Zahradnik's contention stating that it describes an affinity purification step using the claimed sequences "in numerous ways." (Paper 55, 6:1-3).

The purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by the inventor. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991). The inventor can demonstrate possession by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. An inventor needs to show that the inventor was "in possession" of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious. *Lockwood v. American Airlines, Inc.*, 107 F.3d

[6] The PTH(1-8) sequence and any subset of six amino acids therein are unique sequences that are not repeated later in the peptide regardless of whether it is human, rat, porcine, bovine or canine PTH(1-8). (See, Zahradnik '264, ZX 1005, Fig. 1).

1565, 1571-72 (Fed. Cir. 1997). Requiring possession of the invention, and not that which makes it obvious, ensures that the claimed invention does not overreach the scope of the inventor's contribution to the field as described in the patent specification. *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1345 (Fed. Cir. 2000). Depending on the facts of the case, description of a chemical genus can require something more than the description of a single species but less than all species encompassed by the claimed genus. *Cf., Regent of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

For the motions before us, the burden of proof is by a preponderance of the evidence. The burden of showing something by a preponderance of the evidence simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before the trier of fact may find in favor of the party who carries the burden. *Concrete Pipe & Products of California, Inc. v. Construction Laborers Pension Trust for Southern California*, 508 U.S. 602, 622, 113 S. Ct. 2264, 2279 (1993). Yet, in rendering factual findings:

> . . . it is impermissible for the Board to base its factual findings on its expertise, rather than on evidence in the record, although the Board's expertise appropriately plays a role in interpreting record evidence.

Brand v. Miller, 487 F.3d 862, 869 (Fed. Cir. 2007).

4. Findings of Fact

The following findings of fact are in addition to those appearing elsewhere in this decision.

a. Cantor's '780 Specification

24) Cantor '780 states that there exists a well demonstrated clinical need for accurate measurement of PTH. (ZX 1003, 2:21).

25) Cantor '780 states that determining circulating biologically active PTH levels in humans is challenging as PTH is present in the body in low levels and due to the existence of "many circulating fragments." (*Id.* at 3:13-16).

26) According to Cantor, commercially available PTH kits have been shown to produce inaccurate results due to their detection of inactive PTH fragments. (*Id.* at 3:18 – 4:11).

27) Cantor defines the inactive PTH fragments to be avoided as follows:

> The present invention incorporates a discovery that a large, non-whole PTH peptide fragment, **a peptide having an amino acid sequence from between (SEQ ID No.2 [PTH_{3-84}]) and (SEQ ID No. 3 [PTH_{34-84}])**, functions in vivo as a wPTH antagonist or inhibitor (PIN), (see FIG. 12). In other words, the binding of wPTH to PTH receptors and the subsequent biological activity are affected by the presence of this PIN peptide fragment.

(*Id.* at 5:11-16, bold emphasis added).

28) Cantor teaches that a sandwich assay may be used to detect intact PTH as follows:

> A preferred embodiment of the present invention is an immunoradiometric assay (IRMA), often referred to as a sandwich assay, as shown FIGS. 2 and 3. Elements employed

> in such an assay (10) include a capture antibody (12) attached to a solid support (14) and a signal antibody (16) having a label (18), attached thereto (20). Typically, one selects a capture antibody that is specific for C-terminal PTH fragments (22), while the label antibody is specific for the initial wPTH peptide sequence which comprises a domain for adenylate cyclase activation (24), as shown in FIG. 2. However, one could reverse the specificity of these antibodies, as is shown in FIG. 3.

(*Id.* at 9:14-21 and see also Fig. 2 depicted above).

29) Cantor teaches that the signal antibody of the sandwich assay may be prepared through the use of an initial peptide sequence as follows [bracketed matter added]:

> In order to make the signal antibody in the above assay, first one makes a synthetic PTH peptide corresponding either to **hPTH [i.e., human PTH,] (Ser-Val-Ser-Glu-Ile-Gln-Leu-Met), rat PTH (Ala-Val-Ser-Glu-Ile-Gln-Leu-Met), or at least four amino acids in the common sequence**. The selected peptide can play two roles in making an assay, first as a specific source for creating a polyclonal antibody or monoclonal antibody source for signal antibody or capture antibody, and second as part of an affinity purification means for isolating the desired signal antibody or capture antibody.

(*Id.* at 11:6-13, bold emphasis added).

30) Cantor describes the creation of "an affinity-purified anti-(1-6) PTH antibody" by using the initial peptide sequence. (*Id.* at 12:8-10). Cantor however, does not identify the specific sequence used to create the antibody.

b. Status of Cantor Claim 47

31) Cantor claim 47 is not an original claim, but instead was added as part of a preliminary amendment filed concurrent with the filing of the '780 application on August 15, 2003. (ZX 1004).

32) Cantor did not request that its August 15, 2003 preliminary amendment be considered part of the original disclosure. Specifically, Cantor did not file a supplemental oath or declaration under 37 C.F.R. § 1.67 referring to both the application and preliminary amendment filed with the application and Cantor did not pay the requisite surcharge under 37 C.F.R. § 1.16(f).

c. Expert Declarations

i. Zahradnik's Expert, Dr. Hutchinson

33) Dr. Hutchinson testifies that immunology is an extremely unpredictable art. (ZX 1023, ¶ 8).

34) Dr. Hutchinson testifies that one of ordinary skill in the art, reading the '780 application as of its filing date, would not have understood Cantor to be in possession of a method of using any peptide from PTH(1-8) up to PTH(1-33) for the purification of antibodies for use in a whole PTH assay. (*Id.* at ¶ 16).

35) Dr. Hutchinson testifies that the '780 application literally describes the preparation of initial peptides corresponding to hPTH(1-8) or rat PTH(1-8) or at least four (4) amino acids in the common sequence. (*Id.* at ¶¶ 9, 10 and 14).

36) Dr. Hutchinson testifies that PTH(1-9) to PTH(1-33) purification peptides are not inherent to the disclosure of the '780 application as such peptides would not achieve the stated aim of avoiding the detection of PTH fragments. In particular, Dr. Hutchinson states that the use of longer initial peptides would be likely to isolate a variety of different antibodies including antibodies that bind to PTH fragments. (*Id.* at ¶ 11).

37) Dr. Hutchinson testifies that one of ordinary skill in the art would conclude that the use of a PTH(1-33) initial peptide in Cantor's claimed method ***would result*** in antibodies that bind to PTH(7-84), an interfering PTH fragment. (*Id.* at ¶ 6, emphasis added).

ii. Thomas L. Cantor

38) Figure 5 of Cantor's involved '780 application, as well as its parent applications '639 and '422, refer to a whole PTH assay using a PTH(1-8) antibody as a tracer. (ZX 1003, Fig. 5).

39) During reexamination prosecution of Cantor's '566 patent, which issued from the '422 application, Cantor submitted a declaration stating that at the time the '422 application was filed he believed that the tracer antibody was isolated using a PTH(1-8) peptide. (CX 2016, ¶ 2).

40) Cantor testified in his declaration that, during a post-filing date deposition, he became aware that the isolating peptide was actually a PTH(1-9) peptide. (*Id.* at ¶¶ 3-4).

41) Cantor further testified that Figure 5 of the '422 application should be

corrected to refer to a PTH(1-9) antibody. (*Id.* at ¶ 5).

iii. Cantor's Expert, Dr. Woodhead

a. *General testimony regarding PTH assays, Antibodies and Initial Peptides*

42) Dr. Woodhead testifies that at the time of Cantor's invention there were several commercially available intact PTH assays that would cross-react with interfering PTH fragments in a biological sample. (CX 2051, ¶ 38).

43) Cantor's involved claims are directed to a method for producing an antibody that detects whole PTH(1-84) but avoids detecting interfering PTH fragments in a biological sample. (Paper 6).

44) Dr. Woodhead testifies that one of ordinary skill in the art would expect a PTH assay "useful in the determination of intact PTH 1-84 levels in a biological sample" would be able to detect whole PTH while avoiding interfering PTH fragments in the biological sample otherwise the assay would over detect or estimate the amount of biologically active intact PTH. (CX 2051, ¶ 39).

45) Dr. Woodhead testifies that one skilled in the art would understand that the term biological sample means: "a sample from a patient to be tested to determine the intrinsic level of whole $PTH_{1\text{-}84}$." (*Id.* at ¶ 14). Dr. Woodhead further testifies that biological samples would not include samples that have been spiked as that would defeat the purpose of measuring the intrinsic level of whole PTH(1-84) in the samples. (*Id.*).

46) Dr. Woodhead explains that Cantor's antibody affinity purification step is "based on the binding between the antibody and the peptide used to purify the antibody." (*Id.* at ¶ 19).

47) The portion of a protein recognized and bound by an antibody is referred to as an epitope and Dr. Woodhead testifies that epitopes on proteins contain about six to eight amino acids. (*Id.* at ¶ 20).

48) Dr. Woodhead testifies that although it has not been established that a PTH(3-84) fragment exists in biological samples, such a fragment contains six amino acids in common with PTH(1-8), and thus an antibody purified with PTH(1-8) could potentially bind to such a fragment. (*Id.* at ¶ 20).

49) Dr. Woodhead testifies that one of skill in the art would have understood that an antibody purified with PTH(1-8) would not be expected to bind to a PTH fragment sequence beyond the PTH(1-8) sequence, e.g., a PTH(9-84) fragment. (*Id.* at ¶ 20, i.e., no six or more amino acid epitope present).

50) Dr. Woodhead also testifies that one of ordinary skill in the art would have understood that a shorter initial peptide, e.g., PTH(1-8), is more likely to affinity purify an antibody that can specifically detect whole PTH(1-84) while avoiding interfering PTH fragments. (*Id.* at ¶ 34, i.e., larger proteins are more likely to share antibody epitope with interfering PTH fragments).

b. *Testimony Concerning Cantor's Alleged Implicit Support for its Claimed Genus of Initial Peptides*

51) Dr. Woodhead testifies that the '780 application teaches a "flexible, yet principled, way of choosing an affinity purification peptide" that depends upon the particular interfering fragment to be avoided in a particular biological sample. (CX 2051, ¶ 51).

52) Dr. Woodhead directs the Board's attention to the statement in Cantor's '780 specification that one makes an initial peptide corresponding either to human PTH(1-8) or rat PTH(1-8) or at least four amino acids in the common sequence.[7] From this teaching, Dr. Woodhead concludes that the '780 specification describes the use of PTH(1-8) through PTH(1-15). (*Id.* at. ¶¶ 43-44).

53) Dr. Woodhead further testifies that PTH (1-8) to PTH (1-15) is a representative number of species and provides support for the claimed genus of initial peptides PTH (1-8) to PTH (1-33). Specifically, Dr. Woodhead states:

> Because the common N-terminal sequence of human and rat PTH extends to amino acid residue 15 (the '264 patent, Figure 1, Cantor Ex. 2006), one skilled in the art would understand that the '422, '639 and '780 applications describe the use of a group of peptides from PTH (1-8) to PTH (1-15) for antibody purification. One skilled in the art would also understand that the group of peptides from PTH (1-8) to PTH (1-15) is a representative number of species of the group of peptides from

[7] Human PTH (1-8) has the sequence **Ser**-Val-Ser-Glu-Lie-Gln-Leu-Met and rat PTH (1-8) has the sequence **Ala**-Val-Ser-Glu-Lie Gln-Leu-Met.

> PTH (1-8) to PTH (1-33) recited in Cantor claims, which share the necessary common attributes or feature of being able to purify an antibody that can specifically detect whole PTH1-84 while avoiding detecting an interfering non-(1-84) parathyroid hormone fragment in a biological sample.

(*Id.* at. ¶ 44).

54) According to Dr. Woodhead, one of ordinary skill in the art would understand that if a particular fragment from PTH(3-84) to PTH(34-84) exists in a biological sample, the antibody produced by Cantor's method should avoid the fragment.

55) Dr. Woodhead however, states that at the time of the '780 filing, the precise composition of a particular interfering PTH fragment in a biological sample was unclear. (*Id.* at. ¶ 50).

56) Even though the size of the fragments in a particular biological sample was unknown, Dr. Woodhead states that if fragment to be avoided is PTH(34-84), then the upper limit on Cantor's claimed "initial PTH sequence peptide" is necessarily a PTH(1-33) peptide. (*Id.* at ¶¶ 48 and 50).[8]

[8] Dr. Woodhead at ¶ 48 states that the upper limit on the initial peptide is "necessarily" PTH(1-33) but at ¶ 50 states that "a longer peptide, e.g., PTH(1-33) can be used." Given Dr. Woodhead's testimony that the antibody generally requires a six or more amino acid epitope to bind a protein it is likely that a larger initial peptide could be used for a PTH(34-84) fragment. (*Id.* at ¶¶ 20-21, e.g., a PTH(1-8) initial peptide would be expected to isolate antibodies that avoid detecting a PTH(4-84) fragment).

57) Dr. Woodhead concludes that the '780 application describes Cantor's claimed method using the genus of initial peptides ranging from PTH(1-8) to PTH(1-33) by describing a successful purification with a PTH(1-9) antibody and demonstration that the purified antibody achieved the intended goal, by is description of sufficient identifying characteristics, and by the use of a representative number of peptides (PTH(1-8) to PTH(1-15). (*Id.* at. ¶ 53).

5. Analysis of the Parties' Contentions Concerning Cantor's Written Description for the Claimed Genus of Affinity Purification Peptides

Zahradnik contends that Cantor claims 47, 49-51, 53, 54 and 60-68 are not supported under 35 U.S.C. § 112, first paragraph as Cantor's involved '780 application does not support the use of a peptide that is any of a PTH(1-9) to PTH(1-33) for purification purposes. (Paper 30, 2:19-27 and 4:16-27). Cantor provides specific arguments regarding the support for Cantor claim 47 but does not separately address the patentability of the remaining claims.[9] We treat Cantor claims 49-51, 53, 54 and 60-68 as standing or falling together with Cantor claim 47. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("However, where the party urging patentability does not separately address the patentability of each claim corresponding to the count, the Board has reason to treat all claims together.").

Zahradnik contends that Cantor's '780 application does not explicitly, implicitly or inherently provide the necessary support for the claimed genus of initial peptides. Zahradnik's expert, Dr. Hutchinson, testifies that

[9] Cantor Opposition 3 states that claims 49-51, 53, 54 and 60-68 find support for the same reasons that Cantor claim 47 finds support in the '780 application. (Paper 55, 17:14-22).

Cantor's literal description of initial peptides concerned human and rat PTH(1-8) or at least four amino acids in the common sequence. (ZX 1023, ¶ 9). Dr. Hutchinson also testifies however, that the '780 application did not inherently or otherwise convey possession of the broadly claimed genus that extends to PTH(1-33). (ZX 1023, ¶¶ 9-11 14, and 16). In particular, Dr. Hutchinson explains that the use of larger initial peptides would isolate antibodies that jeopardize Cantor's ability to avoid detecting interfering fragments as the use of larger initial peptides would isolate not only those antibodies specific for the N-terminal region of PTH(1-84) but also antibodies specific for different regions, such as regions contained in PTH fragments. (*Id.* at 11). Zahradnik and its expert conclude that Cantor's '780 application does not reasonably convey possession of a method using an initial peptide ranging from PTH(1-9) to PTH(1-33). We find that Zahradnik has provided credible evidence that, if unrebutted, is sufficient to justify the relief sought, the unpatentability of Cantor claims 47, 49-51, 53-54 and 60-68 under 35 U.S.C. § 112, 1st paragraph, lack of written description. 37 C.F.R. § 41.208(b).

Cantor acknowledges that its genus of initial PTH sequence peptides, which includes PTH(1-9) up to PTH(1-33), is not described in *ipsis verbis* language. (Paper 55, 10:21-11:2). Cantor however, contends that its affinity purification step employing a genus of initial peptides is adequately described in numerous ways including:

1) Describing a representative number of initial peptide species that share the necessary common attributes or features of the PTH(1-8) to PTH(1-33) genus;
2) Describing an actual reduction to practice of affinity purification using a PTH(1-9) peptide;

3) Describing sufficient distinguishing identifying characteristics of an initial PTH sequence peptide; and

4) Providing a flexible, yet principled, way of choosing an affinity purification peptide depending on the particular 'non-(1-84) PTH fragment' to be avoided in a particular biological sample.

(*Id.* at 10:15-21 and 14:7-11). Provided below is an analysis of Cantor's alleged implicit and/or inherent description of the claimed genus of initial peptides.

a. Cantor '780 Fails to Describe a Sufficient Representative Number of Initial Peptide Sequences to Support the Claimed Genus

Cantor states that its satisfactory disclosure of a representative number of species coupled with a description of the necessary common attributes or features possessed by the genus is sufficient to demonstrate written description for its genus of initial peptides. (Paper 55, 5:8-21 and 10:15-21). Cantor relies upon Dr. Woodhead's testimony to support its conclusion.

Dr. Woodhead directs our attention to the following statement in its '780 specification:

> In order to make the signal antibody in the above assay, first one makes a synthetic PTH peptide corresponding either to **hPTH (Ser-Val-Ser-Glu-Ile-Gln-Leu-Met), rat PTH (Ala-Val-Ser-Glu-Ile-Gln-Leu-Met), or at least four amino acids in the common sequence**. The selected peptide can play two roles in making an assay, first as a specific source for creating a polyclonal antibody or monoclonal antibody source for signal antibody or capture antibody, and second as part of an affinity purification means for isolating the desired signal antibody or capture antibody.

(Woodhead Dec., CX 2051, ¶ 43, '780, ZX 1003 at 11:6-13, bold emphasis added). Based on the forgoing teaching, Dr. Woodhead concludes that since "the common N-terminal sequence of human and rat PTH extends to amino acid residue 15," one of ordinary skill in the art would understand the '780 application as describing PTH(1-8) to PTH(1-15) for antibody purification. (CX 2051, ¶ 44, and Paper 55, 9:25-28). Dr. Woodhead further states that PTH(1-8) to PTH(1-15) is a representative number of species for the genus of peptides ranging from PTH(1-8) to PTH(1-33) as they share the necessary common attributes or features of being able to detect intact PTH while avoiding detecting interfering PTH fragments in a biological sample. (CX 2051, ¶ 44 and Paper 55, 9:28-10:5). Dr. Woodhead's conclusions are not credibly supported by the record.

Dr. Woodhead's conclusions are based on the premise that "the common N-terminal sequence of human and rat PTH extends to amino acid residue 15." (CX 2051, ¶ 44). Dr. Woodhead appears to have overlooked the fact that rat and human PTH differ in their first amino acid residue. Specifically, as shown below, rat PTH(1-8) has alanine as the first amino acid residue whereas human PTH(1-8) has serine:

Human PTH (1-8): **Ser**-Val-Ser-Glu-Ile-Gln-Leu-Met

Rat PTH(1-8): **Ala**-Val-Ser-Glu-Ile-Gln-Leu-Met

('780, ZX 1003, 11:8-9, and see also Zahradnik '264, Fig. 1). Thus, both the first (1^{st}) and sixteenth (16^{th}) amino acid residues differ between human and rat PTH. Dr. Woodhead however, did not provide a specific theory as to why one of ordinary skill in the art would have included the first (1^{st}) amino acid of either human or rat, which is not in the common sequence, but exclude the sixteenth (16^{th}) amino acid residue which, like the first, is also not in the common sequence. Accordingly, following Dr. Woodhead's

logic, Cantor's '780 specification describes human PTH(1-8), rat PTH(1-8), or at least four amino acids in the sequence human/rat PTH(**2**-15) as opposed to PTH(**1**-15).

Additionally, Dr. Woodhead's conclusion regarding the description of PTH(1-15) is based upon an incorrect construction of the phrase "common sequence." Specifically, the '780 application teaches that one of ordinary skill in the art can make an initial peptide corresponding to either human PTH(1-8), rat PTH(1-8) "or at least four amino acids in the common sequence." ('780, ZX 1003, 11:8-9). The phrase "common sequence" refers to the sequences human and rat PTH(1-8). Accordingly, the specification teaches one of ordinary skill in the art to employ an initial peptide that contains at least four amino acids in common sequence between human PTH(1-8) and rat PTH(1-8), which is PTH(2-8).[10]

Dr. Woodhead does not provide a credible basis for his construction of the term "common sequence" as it appears in Cantor's specification. Accordingly, we do not credit Dr. Woodhead's conclusion that one of ordinary skill in the art would recognize Cantor '780 as describing a genus of peptides ranging from PTH(1-8) to PTH(1-15). *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1092, (Fed. Cir. 1997)(Nothing in the rules

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[10] Our independent construction of the phrase "common sequence" is consistent with the district court's construction of "common sequence." Specifically, the district court stated:

> The phrase, "common sequence of human and rat PTH" is defined in the patent specification as the PTH(2-8) sequence, (identified above as SEQ ID NO.3), which is the same in both rat and human. See '566 Patent at 4:50-55. It does not refer to any other parts that the human and rat PTH sequences may have in common.

(ZX 1043, p. 11, n. 15).

or in jurisprudence requires trier of fact to credit unsupported or conclusory assertions).

Additionally, Dr. Woodhead has failed to demonstrate that a genus extending to PTH(1-15) includes a representative number of species for the genus recited in Cantor's claims, PTH(1-8) to PTH(1-33). Specifically, Dr. Woodhead testifies that PTH(1-8) to PTH(1-15) is a representative number of species as it shares the necessary common attributes with the genus of initial peptides recited in Cantor's claims. (Woodhead Dec., CX 2051, ¶ 44). Dr. Woodhead's conclusion is based on his reasoning that PTH fragments have an N-terminal beginning at positions 4, 7, 8, 10 and 15 and:

> Therefore, using PTH (1-8) to PTH (1-15) peptides in antibody purification would obtain an antibody that can specifically detect whole PTH1-84 while avoiding detecting an interfering non-(1-84) parathyroid hormone fragment in a biological sample, *e.g.*, PTH 4-84, 7-84, 8-84, 10-84 and 15-84 fragments.

(Woodhead Dec., CX 2051, ¶45, cited in Paper 55 at 10:6-11).

Dr. Woodhead's reasoning is conclusory and flawed for as explained below, PTH(4-84) has twelve amino acids in common with PTH(1-15), and may form a complete epitope to which an antibody may bind. Specifically, Dr. Woodhead testifies that epitopes on proteins contain about six to eight amino acids. (CX 2051, ¶ 20). Dr. Woodhead supports his epitope testimony with credible evidence, an introductory text on immunology. (CX 2052, "Immunology An Introduction"). Against this basic knowledge of epitopes, Dr. Woodhead states that an antibody purified with PTH(1-8) can theoretically detect PTH(3-84) as the six amino acids in common between the two peptides may form a complete epitope to which an antibody would bind. (*Id.* at ¶¶ 20-21). Dr. Woodhead and Zahradnik's expert,

Dr. Hutchinson, agree that the more amino acids in common between the initial peptide and fragment, the higher the likelihood that the initial peptide will obtain antibodies that detect interfering fragments. (Woodhead Dec., CX 2051, 33-34 and 50 and Hutchinson Dec., ¶¶ 4-6, 11). Accordingly, it stands to reason that a PTH(1-15) initial peptide with twelve amino acids in common with PTH(4-84) has a higher likelihood of purifying antibodies that detects intact PTH(1-84) as well as interfering PTH(4-84). Furthermore, based on Dr. Woodhead's and Dr. Hutchinson testimony, we find that one of ordinary skill in the art would understand that a PTH(1-33) initial peptide, with thirty amino acids in common with PTH(4-84), is much more likely to purify antibodies that detect intact PTH(1-84) and interfering PTH(4-84). (CX 2051, ¶¶ 33-34 and ZX 1023, ¶ 6 and 11).

b. Cantor's Alleged Actual Reduction to Practice of a PTH(1-9) Initial Peptide Does Not Demonstrate Written Description of the Genus of Initial Peptides PTH(1-8) to PTH(1-33)

Cantor states that the '780 application describes an actual reduction to practice of a PTH(1-9) initial peptide that met all the limitations of Cantor's claims. (Paper 55, 7:3-6 and ¶ 65). For the reasons provided below, we find that Cantor's '780 application does not describe an actual reduction to practice of a PTH(1-9) initial peptide sequence, and that even if it did, Cantor has failed to demonstrate that such a species demonstrates written description for the genus of initial peptides ranging from PTH(1-8) up to PTH(1-34).

According to Cantor and Dr. Woodhead, Figure 2 demonstrates that an anti-PTH antibody "binds to an epitope within (1-9) PTH sequence is

used as a tracer element." (*Id.* at 7:7-9, emphasis added, CX 2003, ¶ 40). Cantor Figure 2 is described as a diagrammatic view of a whole PTH assay using the inventive antibody as a tracer element. (ZX 1003, 7:25-26). Cantor '780 further states that the antibody is "specific for the initial wPTH peptide sequence which comprises a domain for adenylate cyclase activation (24) as shown in Figure 2." (*Id.* at 9:17-20). Cantor '780 states that the adenylate cyclase activation domain is amino acid residues 1 to 7. Thus, Dr. Woodhead is correct in stating that Cantor Figure 2 demonstrates antibody binding within PTH(1-9) as binding specific to PTH(1-7) is "within" PTH(1-9). We do not credit Dr. Woodhead's testimony to the extent he suggests that Figure 2 conclusively demonstrates binding to PTH(1-9) as Figure 2 is merely a general depiction of a sandwich assay that does not particularly identify the specific epitopes bound by the antibodies and the specification's description of the figure indicates that the antibody is specific for PTH(1-7), the adenylate cyclase activation domain.

Dr. Woodhead testifies that the skilled person would understand that the anti-PTH antibody of Figure 2 could be purified using a PTH(1-9) peptide. (CX 2011, ¶ 40). Dr. Woodhead's testimony is technically correct, the antibody of Figure 2 can be obtained via affinity purification using a PTH(1-9) initial peptide. We do not credit Dr. Woodhead's testimony however, to the extent he suggests that the antibody of Figure 2 was necessarily obtained using a PTH(1-9) initial peptide, e.g., a PTH(1-8) antibody could have been used to obtain an antibody that binds the PTH(1-7) adenylate cyclase activation domain. (ZX 1023, ¶ 4, an initial peptide of sufficient length generates antibodies specific for various epitopes along the length of the initial peptide and CX 2051, ¶ 20 and CX 2052, epitopes contain about six to eight amino acids).

Cantor directs our attention to Figure 5 of its application as further evidence of an actual reduction to practice for the claimed genus. (Paper 55, 7:11-13). Cantor '780 Figure 5 provides a graph of comparing Cantor's whole PTH assay with Nichols' Intact PTH assay. The graph states that it is based on a "Whole PTH Assay (with PTH 1-8 Antibody as Tracer) versus Nicohls' Intact PTH Assay (with PTH 7-84) Interference." (ZX 1003, Fig. 5). Accordingly, Cantor '780 Figure 5, on its face, does not evidence an actual reduction to practice for PTH(1-9).

Counsel for Cantor directs our attention to an ex parte declaration by Cantor declaring that the testing data used to generate Figure 5 employed an antibody that was purified using a PTH(1-9) peptide. (Paper 55, 7:11-13 and Cantor Dec., CX 2016). Cantor is correct that the declaration states that the initial peptide used to prepare the antibody of Figure 5 was PTH(1-9) however, the declaration demonstrates that at the time the '780 application was filed, Cantor believed the initial peptide used was PTH(1-8). (CX 2016,¶ 2 "The term 'PTH 1-8 antibody' was used to refer to this antibody because I then believed the antibody had been isolated by Dr. Ping Gao and his co-workers using a PTH 1-8 peptide for affinity purification of the antibody."). The issue before the panel is whether Cantor's as-filed '780 application describes the genus of initial peptides recited in Cantor claim 47. Cantor has failed to sufficiently explain how Cantor's post-filing realization that the identified antibody was purified using a PTH(1-9) initial peptide, as opposed to the PTH(1-8) initial peptide identified in the '780 application, is germane to the written description issue before us.

Additionally, even if Cantor's allegations concerning an actual reduction of a PTH(1-9) initial peptide are correct, Cantor fails to explain how the actual reduction to practice of the PTH(1-9) initial peptide

demonstrates that Cantor's '780 application provide sufficient written description of the genus of peptides ranging from PTH(1-8) up to PTH(1-34).

c. Cantor '780 Failed to Provide Sufficient Identifying Characteristics Sufficient to Demonstrate That it Described The Claimed Genus of Initial Peptides

Cantor states that its '780 application evidences possession of the genus of initial peptides by describing a sufficient number of distinguishing identifying characteristics. (Paper 55, 4:15–5:4 and 7:17-21). Cantor states that its '780 application defines the PTH fragments to be avoided as having an amino acid sequence from between PTH(3-84) to PTH(34-84). (*Id.* at 8:20-25). Cantor states that its affinity purification method solves the problem caused by the interfering fragment in a biological sample. (*Id.* at 9:1-3). Cantor justifies the newly claimed genus of initial peptides stating that:

> In addition, given the teaching that the non-whole PTH peptide fragment to be avoided is a peptide having an amino acid sequence from between PTH_{3-84} and PTH_{34-84}, the skilled person would understand that one can use an "initial PTH sequence peptide" that is up to (1-33) PTH N-terminal fragment to purify an anti-PTH antibody for specifically detecting whole PTH_{1-84} while avoiding detecting an interfering non-(1-84) PTH fragment.

(*Id.* at 9:8-12). Cantor cites Dr. Woodhead's testimony as support for its conclusion. (Paper 55, fact ¶ 58 citing Woodhead Dec., CX 2051, ¶ 36). Cantor and Dr. Woodhead's conclusions are not credibly supported by the record.

Dr. Woodhead testifies that at the time of filing, it was known in the art that interfering PTH fragments existed in patient samples and that existing assays cross-reacted with the fragments, i.e., reported false readings of intact PTH. (CX 2051, ¶ 38). Dr. Woodhead testifies that to be useful in the determination of intact PTH 1-84 levels in a biological sample means that the antibody avoids detecting interfering fragments lest the assay over detect or estimate the actual intact PTH 1-84 levels. (*Id.*).

The '780 application teaches that interfering fragments range in size from PTH(3-84) to PTH(34-84). Dr. Woodhead testifies that one of ordinary skill in the art at the time of the invention would not have known in advance what particular interfering fragments were present in a particular biological sample. (CX 2051, ¶ 50 ". . . the precise composition of a particular 'non-(1-84) PTH fragment' in a particular biological sample was unclear.").

An initial PTH(1-33) peptide sequence has twenty-seven (27) amino acids in common with an interfering PTH(7-84) fragment, and even more with an interfering PTH(4-84) fragment. The evidence of record demonstrates that epitopes on proteins contain about six (6) to eight (8) amino acids. (CX 2051, ¶ 20, CX 2052 and 2053).[11] Accordingly, as PTH(1-33) and PTH(7-84) share a sufficient number of amino acids in their common sequence to share a complete epitope, a initial PTH(1-33) peptide

[11] We recognize that it has been theorized that protein epitopes could be as large as twelve (12) or even up to twenty (20) amino acids. (CX 2051, ¶ 20 and CX 2052). We focus on the six to eight amino acid epitopes as the record shows that such epitopes are known in the art as opposed to theorized. Further, it is not clear on this record how Cantor's described PTH(1-8) initial peptide would function if the only antibodies capable of binding PTH required a twelve (12) or twenty (20) amino acid epitope.

sequence is capable of isolating antibodies that bind to interfering PTH(7-84) fragments.

We credit the testimony of Zahradnik's expert, Dr. Hutchinson, who declares that affinity purification with a PTH(1-33) initial peptide sequence "would result" in an antiserum that contains antibodies that bind within the region of PTH(1-33) and that the antiserum would include antibodies that bind to PTH(7-84). (ZX 1023, ¶ 6). In contrast, we do not credit Cantor's expert, Dr. Woodhead, to the extent he contradicts Dr. Hutchinson as Dr. Hutchinson's conclusions are consistent with the underlying record whereas Dr. Woodhead's conclusions are not. We find that Cantor has failed to demonstrate on this record that it provided sufficient identifying characteristics to demonstrate that it described the genus of initial peptides that extends up to PTH(1-33).

d. Cantor's Approach to Affinity Purification Peptides Does Not Implicitly Describe the Claimed Genus

Cantor contends that its '780 application teaches a flexible and operable approach to selecting an affinity purification peptide and that this approach demonstrates that Cantor describes the claimed genus of initial affinity purification peptides. (Paper 55, 13:7-9 and 17:4-13). Cantor's specific arguments regarding its flexible approach are discussed below.

Cantor states that its explicit teaching of a PTH(1-8) peptide is meant to be exemplary only. Cantor contends that if the application intended to be limited to such a peptide the application would not have used the more generic term "initial PTH sequence peptide." (*Id.* at 12:12-22). Cantor '780 is not limited to PTH(1-8). Specifically, Cantor '780 teaches that the initial

PTH sequence peptide can be human PTH(1-8), rat PTH(1-8) or at least four amino acids in the common sequence. Accordingly, Cantor's '780 specification employs the term "initial PTH sequence peptide" to refer to a genus of peptides, albeit not the genus presented in Cantor claim 47.

Cantor contends that the '780 specification teaches a flexible approach to the initial peptides as one of ordinary skill in the art would know how to select an affinity purification peptide to avoid particular fragments. (*Id.* at 13:7 – 14:1). In particular, Cantor states that one of ordinary skill in the art would understand that a shorter affinity purification peptide, e.g., PTH(1-8), can be used to avoid a PTH(7-84) fragment but if the fragment is PTH(34-84) one of ordinary skill in the art could select a longer affinity purification peptide, such as PTH(1-33). (*Id.* at 14:1-6 and 17:8-11). We fail to understand Cantor's reasoning as it presumes one of ordinary skill in the art would know in advance which particular fragment is present in a particular biological sample.

Cantor '780 teaches that prior art assays failed to accurately measure intact PTH as the assays detected the presence of both intact PTH as well as biologically inactive fragments. Dr. Woodhead testifies that a PTH assay that is useful in the determination of intact PTH(1-84) levels in a biological sample would specifically detect whole PTH(1-84) while avoiding detecting the interfering fragments. (CX 2051, ¶ 39). Cantor and Dr. Woodhead acknowledge that one of ordinary skill in the art would not have known in advance which particular fragments were present in a particular biological sample and that the composition of fragments can vary in biological samples. (Paper 55, 13:20-21, 14:13-15 and CX 2051, ¶ 50 and 52). Indeed, Dr. Woodhead explicitly states that the '780 application describes tests for determining the level of whole PTH(1-84) in patient samples that have not

been "spiked" with an interfering fragment. Accordingly, one of ordinary skill in the art would not have known in advance whether a particular sample contained large interfering PTH fragments, e.g., PTH(4-84), which require short affinity purification peptides or small interfering PTH fragments, e.g., PTH(34-84), which allow for the use of larger affinity purification peptides.

Cantor alleges that the fact that its '780 application teaches goat anti-(1-6) antibodies further shows that the disclosure of the '780 application is not limited to PTH(1-8) initial peptides. Cantor does not direct our attention to credible evidence in support of this conclusion. Furthermore, as discussed above, Cantor's '780 specification is not limited to the use of PTH(1-8) initial peptides but includes human PTH(1-8), rat PTH(1-8) and at least four amino acids in the common sequence between rat PTH(1-8) and human PTH(1-8).

Additionally, at oral hearing, a question arose as to whether Cantor claim 47 was an original claim and formed a part of the '780 specification. (Paper 87, 13:28-14:16). A review of the '780 prosecution history file reveals that it is not an original claim but was filed as part of a preliminary amendment filed August 15, 2003. (ZX 1004). Cantor did not submit a supplemental oath or declaration referring to the preliminary amendment acknowledging the duty to disclose all information known to be material as of the filing date of the newly added subject matter, i.e., the '780 application filing date. Accordingly, the subject matter added by the preliminary amendment does not form part of the original disclosure. *See, e.g.*, Manual of Patent Examining Procedure, § 608.04(b), "New Matter by Preliminary Amendment" (2008).

e. Zahradnik Has Met Its Burden of Proof that Cantor Claims 47, 49-51, 53, 54 and 60-68 Are Unpatentable Under 35 U.S.C. 112, First Paragraph, Written Description

We grant Zahradnik Substantive Motion 3 as Zahradnik has established by at least a preponderance of the evidence that Cantor claims 47, 49-51, 53, 54 and 60-68 are unpatentable under 35 U.S.C. § 112, first paragraph, lack of written description. In particular, we credit the testimony of Zahradnik's expert, Dr. Hutchinson, who testifies that the '780 application does not explicitly or inherently describe Cantor's genus of initial peptide sequences that extends from PTH(1-8) to PTH(1-33). While we credit the testimony of Dr. Woodhead with respect to his general discussion of affinity purification we do not credit Dr. Woodhead's testimony with respect to his conclusions regarding Cantor's description of the claimed genus of initial peptide sequences. Specifically, we find that Dr. Woodhead's testimony concerning the alleged inherent or implicit description of the peptides is not supported by the record.

B. Zahradnik Motion 2: Motion for No Interference-in-Fact

Zahradnik Motion 2 moves for judgment on the grounds that there is no interference-in-fact between the parties' involved claims. (Paper 29, 1:2-3).

Generally, an interference exists where there is a question of priority as between two parties claiming the same patentable subject matter such that two patents on the claimed subject matter should not exist. The record however, has changed substantially since the Examiner recommended that an interference be declared. For example, our analysis of Zahradnik

Substantive Motion 3, motion for unpatentability based on lack of written description, demonstrates that almost all of Cantor's involved claims are unpatentable. Specifically, Cantor claims 47, 49-51, 53, 54 and 60-68 have been held unpatentable. Taking into account the changed record, we dismiss as moot that portion of Zahradnik's motion that requests no interference-in-fact with respect to Cantor claims lacking written description, claims 47, 49-51, 53, 54 and 60-68. We review Zahradnik Motion 2, motion for no interference-in-fact, solely to determine whether the record is sufficient to establish the existence of interfering subject matter as between Zahradnik's involved claims and Cantor's sole remaining claim, claim 59.

1. Legal Principles

An interference in fact exists when an application and a patent or an application and another application each have at least one claim directed to patentably indistinct subject matter. The existence of an interference in fact is initially determined by applying the so called "two-way test" of 37 C.F.R. § 41.203(a)(2004):

> An interference exists if the subject matter of a claim of one party would, if prior art, have anticipated or rendered obvious the subject matter of a claim of the opposing party and vice versa.

Thus, the subject matter of a claim of one party is assumed to be prior art with respect to the claimed subject matter of the opponent. An evaluation is made to determine if the opponent's subject matter is anticipated by or obvious from the subject matter of the party's claims. The analysis is then repeated with the opponent's claimed subject matter assumed to be prior art. No interference-in-fact is shown if the outcome of

either evaluation is that one party's subject matter is neither anticipated nor obvious from the others.

Anticipation is established only when a single prior art reference discloses all elements of the claimed invention. *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990). Obviousness under 35 U.S.C. § 103 requires that one identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Obviousness also requires an analysis of whether the prior art would have revealed that in carrying out the claimed method those of ordinary skill in the art would have had a reasonable expectation of success. *In re Vaeck*, 947 F.2d. 488, 493 (Fed. Cir. 1991).

2. Findings of Fact

The following findings of fact are supported by at least a preponderance of the evidence and are in addition to those findings presented elsewhere in this decision.

a. Cantor Requested that Claim 59 Be Designated as Not Corresponding to Count 1, i.e., Not Part of the Interference

58) Cantor's List of Intended Motions requested authorization to file a motion to designate claim 59 as not corresponding to Count 1, i.e., Zahradnik claim 1 does not anticipate or render obvious Cantor claim 59. (Paper 22, 1:7-8).[12]

[12] Cantor's proposed motion was contingent upon a denial of a motion to change the count to include Cantor claim 47, which encompasses a PTH(1-

59) Cantor represented at oral hearing that claim 59 was quite different from the interfering subject matter and should not be part of the interference. Specifically, Cantor stated:

> Mr. Kreeger [Cantor]: Although I would say that we have a motion pending to designated claim 59 and we would certainly like that motion heard before judgment were entered because that claim is quite different from the one that's in interference, particularly if you don't grant the motion to substitute a count.

(Paper 87, 27:12-16).

b. Dr. Woodhead Declaration

60) Zahradnik's involved claims are directed to a "method for producing an antibody to the N-terminal portion of (1-84) PTH useful in the determination of intact PTH 1-84 levels in a biological sample." (Zahradnik Clean Copy of Claims, Paper 9, claims 1-6).

61) Dr. Woodhead testifies that Zahradnik's specification describes its inventive method and antibodies as having particular advantages including greater affinity for PTH than prior art antibodies and negligible cross-reactivity with large non-(1-84) molecular forms of PTH. (CX 2051, ¶ 40). Dr. Woodhead cites the following portion of Zahradnik's specification as support for his testimony:

> In this regard, the present invention is directed to certain novel antigens, antibodies, and methods for producing antibodies that are <u>useful in determining bioactive intact PTH levels in a sample fluid</u>, such as serum, plasma or cell culture media. The antigens, antibodies and methods of the present invention have

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8) initial peptide. (Id. at 4-6). The Board deferred consideration of Cantor's request to the priority phase of the interference. (Paper 24, 2:17-22).

> the particular advantages of possessing greater affinity for PTH, and in particular, are designed to have a novel recognition for amino acid residues extending beyond the first N-terminal PTH residue than prior art antibodies specific to bioactive intact PTH, and further have negligible cross-reactivity with the large non-(1-84) molecular forms of PTH.

(CX 2051, ¶ 40 citing '264, CX 2006, 2:49-61, emphasis in Dr. Woodhead's Declaration).

62) Dr. Woodhead concludes that one of ordinary skill in the art would understand that Zahradnik's claimed method requires the production of an antibody to detect intact or whole PTH while avoiding detecting or having negligible cross-reactivity with large non-(1-84) forms of PTH in order to accurately measure the intact or whole PTH levels in the biological sample. (*Id.* at ¶ 41).

c. Sukovaty (2006)

63) Sukovaty et al. ("Sukovaty") published an article in 2006 that described the testing of PTH immunoassays kits for their cross-reactivity with inactive PTH fragments, PTH(3-84) and PTH(7-84). (ZX 1031, abstract).

64) Sukovaty tested three different antibodies: i) "Kit B" a PTH(1-6) antibody from Scantibodies, the real party in interest for Cantor; ii) "Kit C" a PTH(1-12) antibody from Immutopics, the real party in interest for Zahradnik, and iii) "Kit A" a PTH(1-34) antibody from Nichols Institute Diagnostics. (*Id.* at p. 262, Table 1).

65) Sukovaty reported that Scantibodies' (Cantor's) PTH(1-6) antibody has "no observable interference by PTH(3-84) or PTH(7-84) at all the concentrations tested." (*Id.* at p. 267, col. 1).

66) Sukovaty reported that Immutopics' (Zahradnik's) PTH(1-12) antibody provided the following results:

> Kit C [PTH(1-12)] results indicated that the presence of PTH(3-84) affected quantification at all the concentrations of PTH(1-84) tested. The presence of PTH(7-84) affected the quantification of PTH(1-84) at lower concentrations (15 and 75 pg/ml), but not at a higher concentration (750 pg/ml).

(*Id.*).

67) Sukovaty found that Nichols' kit with a PTH(1-34) antibody was affected by the presence of both PTH(3-84) and PTH(7-84) due to the cross-reactivity of the antibody with the fragments. (*Id.*).

68) Sukovaty concluded that Scantibodies' (Cantor's) PTH(1-6) antibody produced the best results with the lowest cross-reactivity and the results were more accurate and reproducible than the kits with PTH(1-12) and PTH(1-34). (*Id.*).

3. Analysis

Zahradnik Motion 2 requests a determination of no interference-in-fact between Zahradnik and Cantor's involved claims and analyzes the question of no interference-in-fact from the point of view that Zahradnik's involved claims fail to anticipate or render obvious Cantor's claims. Cantor represents that Cantor claim 59 should be undesignated from Count 1, i.e.,

Cantor represents that Zahradnik claim 1, which is Zahradnik's sole independent claim, does not anticipate or render obvious Cantor claim 59. (Paper 22, 1:7-8 and Paper 87, 27:12-16). Given that both parties have effectively requested a determination that Cantor claim 59 be held not to interfere-in-fact with Zahradnik's, we exercise our discretion and analyze whether Cantor's remaining claim anticipates or renders obvious Zahradnik's involved claims.

Cantor claim 59 and Zahradnik's involved claims are directed to methods of producing antibodies useful in detecting whole PTH (1-84). Useful in detecting whole PTH means that the antibody detects whole or intact PTH(1-84) but avoids detecting or has negligible cross-reactivity with large interfering PTH fragments such that intact PTH can be accurately measured in a biological sample. (CX 2051, ¶ 41).

Zahradnik states, and Cantor generally agrees, that removing the first two amino acids from PTH results in a PTH that possesses virtually no biological activity. Zahradnik further states that such fragments are typically present in blood samples and that these fragments interfere with the ability to detect whole PTH(1-84). (Paper 28, 1:12-18, Paper 29, 1:16-20, and Paper 87, 15:13-19). PTH(3-84) is a PTH fragment lacking the first two N-terminal amino acids and is specifically identified by Cantor as an interfering fragment.

Cantor claim 59 obtains its antibodies using affinity purification peptides selected from the group consisting of human PTH(1-8), rat PTH(1-8) or at least four amino acids in the common sequence. Unlike Cantor's claim 59, Zahradnik claims a method involving affinity purification peptides selected from the group consisting of human, rat, canine or bovine PTH(1-12).

We hold that PTH(1-12) is novel over PTH(1-8) as a PTH(1-12) initial affinity purification peptide is not a description of a PTH(1-8) initial affinity purification peptide. Accordingly, the key issue is whether Cantor's method employing PTH(1-8) affinity purification peptide would have rendered obvious Zahradnik's method which uses a PTH(1-12) peptide.

Cantor's initial affinity purification peptide can be as long as PTH(1-8). A PTH(1-8) antibody has six amino acids in common with an interfering PTH(3-84) fragment. Epitopes on proteins generally contain six to eight amino acids. Accordingly, it is possible that a PTH(1-8) affinity purification peptide could obtain an antibody that cross-reacts with a PTH(3-84) fragment. (CX 2051, ¶¶ 20-21).

One of ordinary skill in the art would have recognized that the longer the affinity purification peptide, the higher the likelihood of obtaining antibodies that cross-react with interfering fragments, such as PTH(3-84). (CX 2051, ¶¶ 33-34, and ZX 1023, ¶ 11). Specifically, one of ordinary skill in the art would have recognized that the use of long PTH affinity purification peptides would result in the isolation of antibodies that detect PTH fragments. (ZX 1023, ¶ 11).

PTH(1-12) has ten amino acids in common with PTH(3-84), which is a sufficient number of amino acids to share a common complete epitope. Given that one of ordinary skill in the art would have understood that PTH(1-8) affinity purification peptides may isolate antibodies that cross-react with an interfering PTH(3-84) fragment and that PTH(1-12) has even more amino acids in common with PTH(3-84), one of ordinary skill in the art would have ***lacked*** a reasonable expectation of success of using PTH(1-12) to isolate antibodies that have negligible cross-reactivity with large PTH fragments, such as PTH(3-84).

Our conclusion that one of ordinary skill in the art at the time of the invention lacked a reasonable expectation of success is consistent with the findings made by Sukovaty in its post-filing testing of PTH(1-12). As stated by Zahradnik:

> **At page 4, lines 14-23, Cantor urges that the findings of the Sukovaty article show that antibodies made using Zahradnik's claims avoid detecting a non(1-84) parathyroid hormone fragment**. The response is that the very same Sukovaty article, however, showed that Immutopics' Bioactive Intact PTH kit produced in accordance with the Zahradnik claims was shown to have **substantial cross reactivity of 48% with PTH3-84** (MF 68-69) and further **lack absolute specificity for whole PTH**.

(Zahradnik Reply 2, Paper 66, 2:19-24, emphasis in original). As evidenced by Sukovaty, PTH antibodies that bind to larger N-terminal regions have higher levels of cross-reactivity, i.e., PTH(1-34) antibody is more cross-reactive than PTH(1-12), which is more cross-reactive than PTH(1-6) for PTH(3-84) and PTH(7-84) interfering fragments. (ZX 1031).

We hold that Cantor claim 59 does not render obvious Zahradnik's involved claims. We grant Zahradnik Substantive Motion 2 solely to the extent it requests a determination that Cantor claim 59 does not interference-in-fact with Zahradnik's involved claims.

As the record fails to demonstrate that the parties' remaining claims are directed to the same patentable subject matter, it is appropriate to enter a judgment of no interference-in-fact. A judgment of no interference-in-fact between the parties' remaining claims accompanies this decision.

C. Cantor Contingent Responsive Motion 4

Cantor Contingent Responsive Motion 4 requests that claim 47 be replaced with one of proposed claims 69-71 if Zahradnik Motion 1, 2 and/or 4 are granted. (Paper 48). Proposed claims 69-71, like claim 47, select an antibody from antiserum using an affinity purification peptide ranging from PTH(1-8) to PTH(1-33). (Paper 48, fact ¶¶ 4-7). We hold that Cantor's proposed claims do not overcome the written description problem identified in Zahradnik Substantive Motion 3. We ***deny*** Cantor Contingent Responsive Motion 4 for the reasons provided above with respect to Zahradnik Substantive Motion 3.

D. Zahradnik Substantive Motions 1 and 4 for Judgment

Zahradnik Substantive Motion 1 moves for judgment against Cantor's involved claims based on an alleged lack of compliance with § 135(b). (Paper 28). Zahradnik Substantive Motion 4 moves for judgment against Cantor's involved claims based on an alleged lack of compliance with § 112, first paragraph, enablement. (Paper 31).

We dismiss Zahradnik Substantive Motions 1 and 4 as moot in light of our determination that Cantor's sole remaining claim does not interfere-in-fact with Zahradnik's involved claims. This decision is without prejudice to the Examiner of Cantor claim 59 considering the issues raised in Zahradnik's motions, e.g., whether Cantor claim 59 lacks enablement.

E. Cantor Substantive Motions 1, 2 and 3

Cantor Substantive Motion 1 requests benefit of earlier filed applications. (Paper 36). Cantor Substantive Motion 2 requests that the Count be broadened to include Cantor claim 47. (Paper 37, 1:2-4). The

relief requested in Cantor Substantive Motions 1 and 2 is moot in light of our determination that Cantor claim 47 lacks written description and that Cantor's remaining claim does not interfere-in-fact with Zahradnik's involved claims. We dismiss Cantor Substantive Motions 1 and 2 as moot.

Cantor Substantive Motion 3 moves to correct the inventorship of the '780 application by adding Dr. Ping Gao as an inventor. (Paper 38, 1:2-5). As there is no longer an interference-in-fact between Cantor and Zahradnik, we dismiss Cantor's motion to correct inventorship as moot. This dismissal is without prejudice to Cantor raising the issue before the Examiner upon resumption of ex parte prosecution.

V. Order

It is:

ORDERED that Zahradnik Substantive Motion 3 for judgment against Cantor claims 49-51, 53, 54 and 60-68 based on lack of written description is granted.

FURTHER ORDERED that Zahradnik Substantive Motion 2 for judgment of no interference-in-fact is granted with respect to Cantor claim 59 and dismissed as moot with respect to Cantor claims 49-51, 53, 54 and 60-68.

FURTHER ORDERED that Zahradnik Substantive Motion 1 for judgment against Cantor based on §135(b) is dismissed as moot.

FURTHER ORDERED that Zahradnik Substantive Motion 4 for judgment against Cantor based on lack of enablement is dismissed as moot.

FURTHER ORDERED that Cantor Substantive Motion 1 for benefit of earlier filed applications is dismissed as moot.

FURTHER ORDERED that Cantor Substantive Motion 2 to

substitute a count is dismissed as moot.

FURTHER ORDERED that Cantor Substantive Motion 3 to correct inventorship is dismissed as moot.

FURTHER ORDERED that Cantor Contingent Responsive Motion 4 to add claims is denied.

cc (via electronic filing):

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